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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/781,296	01/13/1997	JOHN B. HARLEY	OMRF161	8073

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EXAMINER

CLOW, LORI A

ART UNIT PAPER NUMBER

1631

DATE MAILED: 08/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

08/781,296

Applicant(s)

HARLEY ET AL.

Examiner

Lori A. Clow, Ph.D.

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 25 March 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 27 and 29-40 is/are pending in the application.
- 4a) Of the above claim(s) 30-40 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 27 and 29 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Applicants' arguments, filed 25 March 2005, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claims 27 and 29-40 are currently pending. As stated in the previous Office Action and in several previous Office Actions, claims 30-40 are withdrawn from consideration for being directed to a non-elected invention. Claims 27 and 29 are hereby examined on the merits.

Applicant is reminded that the initial Election/Restriction mailed 24 December 1997 included and Election of Species as it pertained to the sequences listed in current claim 27. As no prior art is available for SEQ ID NO:27, Applicant is hereby entitled to consideration of the claims to additional species. In this respect, a new sequence search has been performed for the additional species.

#### **Response to Applicant's Arguments**

Applicant's arguments in response to the 35 USC 102 rejections over Middledorp, the '353 patent, and the '522 patent, respectively, have been considered and are deemed persuasive. The prior art does not teach the specific sequence of SEQ ID NO:27.

Applicant's arguments in response to the 35 USC 103 rejections over Middledorp have been withdrawn in view of Applicant's arguments (see above).

#### **Claim Rejections - 35 USC § 112-Written Description**

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 27 and 29 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant

Art Unit: 1631

art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification discloses SEQ ID NOs: 1, 2, 3, 7, 13-23, and 25-38, as recited in the instant claims. SEQ ID NOs: 1, 2, 3, 7, 13-23, and 25-38, per se meet the written description and enablement provisions of 35 USC 112, first paragraph. However, claims 27 and 29 are directed to encompass combinations of these sequences, as well as sequences larger than the recited sequences. None of these additional sequences meet the written description provision of 35 USC 112, first paragraph. The specification provides insufficient written description to support the genus encompassed by the claim. This is a rejection based on a lack of WRITTEN DESCRIPTION.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of *the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

Therefore, only SEQ ID NOs: 1, 2, 3, 7, 13-23, and 25-38 but not the full breadth of the claims meet the written description provision of 35 USC 112, first paragraph. The species specifically disclosed are not representative of the genus because the genus is highly variant. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC 112 is severable from its enablement provision. (See page 1115.)

### **Claim Rejections - 35 USC § 102**

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Art Unit: 1631

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 27 and 29 are rejected under 35 U.S.C. 102(b) as being anticipated by Ebihara et al. (Nippon Kagaku Zasshi (1969) Vol. 90, No. 8, pages 819-823 ; see STN search page). Ebihara et al. disclose a peptide molecule consisting of about 40 amino acids or less and comprising the peptide sequence GAGAGAGAGAGAGAGAGAGAGA (SEQ ID NO:7).

Claims 27 and 29 are rejected under 35 U.S.C. 102(b) as being anticipated by Stuber et al. (International Immunology (1995) Vol. 7, No. 4, pages 653-663). Stuber et al. disclose a peptide molecule consisting of about 40 amino acids or less and comprising the peptide sequence RPQKRPS (SEQ ID NO: 15; page 658, sequence 39).

Stuber et al. also disclose a peptide molecule consisting of about 40 amino acids or less and comprising the peptide sequence QKRPSIGCKGTHGGTG (SEQ ID NO:16; page 658, sequence 39).

Stuber et al. also disclose a peptide molecule consisting of about 40 amino acids or less and comprising the peptide sequence GMAPGPGP (SEQ ID NO:34; page 658, sequence 23)

Stuber et al. also disclose a peptide molecule consisting of about 40 amino acids or less and comprising the peptide sequence PQGPLRE (SEQ ID NO: 35; page 658, sequence 23).

Claims 27 and 29 are rejected under 35 U.S.C. 102(b) as being anticipated by Middeldorp (WO 94/06912). Middeldorp discloses a peptide molecule consisting of about 40 amino acids or less and comprising the peptide sequence RARGRGRGRGEKRPRS (SEQ ID NO:20; page 40, SEQ ID NO: 2)

Middeldorp discloses a peptide molecule consisting of about 40 amino acids or less and comprising the peptide sequence RPPPGRRPFFHPVGEADYFEYHQEG (SEQ ID NO: 22; pages 41-42, SEQ ID NO: 5)

Art Unit: 1631

Claims 27 and 29 are rejected under 35 U.S.C. 102(b) as being anticipated by Chen et al. (Virology (1994) Vol. 205, pages 486-495). Chen et al. disclose a peptide molecule consisting of about 40 amino acids or less and comprising the peptide sequence GKHRGQGGSN (SEQ ID NO: 28; page 489, Figure 1(A)).

Chen et al. disclose a peptide molecule consisting of about 40 amino acids or less and comprising the peptide sequence QGGSNPK (SEQ ID NO: 29; page 489, Figure 1(A)).

Chen et al. disclose a peptide molecule consisting of about 40 amino acids or less and comprising the peptide sequence NPKFENIA (SEQ ID NO: 30; page 489, Figure 1(A)).

Claims 27 and 29 are rejected under 35 U.S.C. 102(b) as being anticipated by Stuber et al. (European Journal of Immunology (1992) Vol. 22, pages 2697-2703). Stuber et al. disclose a peptide molecule consisting of about 40 amino acids or less and comprising the peptide sequence RVTVCSEDDG (SEQ ID NO: 37; page 2701, Table 2, 1<sup>st</sup> sequence).

No claims are allowed.

### **Conclusion**

Claims 27 and 29 are rejected under 35 USC 102(b) for the reasons stated above. The following sequences appear to be free of the prior art: SEQ ID NOs: 1, 2, 3, 13, 14, 17-19, 21, 23, 25-27, 29, 31-33, 38, and 38.

### **Inquiries**

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The Central Fax Center Number is (571) 273-8300.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lori A. Clow, Ph.D., whose telephone number is (571) 272-0715. The examiner can normally be reached on Monday-Friday from 10 am to 6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, Ph.D., can be reached on (571) 272-0718.

Art Unit: 1631

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

August 3, 2005  
Lori A. Clow, Ph.D.  
Art Unit 1631  
*Lori A. Clow*

  
MARY K. ZEMAN  
PRIMARY EXAMINER  
*Aug 31*  
*8/3/05*